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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,811	12/08/2003	Thomas Hemmerling		2726
7590	08/04/2005		EXAMINER	
Fay Kaplun & Marcin, LLP Suite 702 150 Broadway New York, NY 10038			GREENE, DANA D	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/730,811	HEMMERLING ET AL.
	Examiner Dana D. Greene	Art Unit 3762

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 08 December 2003.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-23 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 13-18 and 21 is/are allowed.  
 6) Claim(s) 1-12, 19, 20, 22 and 23 is/are rejected.  
 7) Claim(s) 13-15 and 21 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 08 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5-27-04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Claim Objections***

Claims 14 and 21 objected to because of the following informalities: unclear phrase usage. Examiner objects to the use of the phrase “train-of-four twitches” in claims 14 and 21 because the phrase has not been clearly defined. Appropriate clarification is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 5, 12, 19, 20, 22, and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Gozani et al. (US 2002/0173828 A1, hereinafter “Gozani”). Gozani is considered to disclose:

at least one neurostimulator to apply muscle-activating stimulation signals to a patient’s body via at least one electrode (see col. 5, para. 0020, Gozani). The disclosed neuromuscular electrode is considered to anticipate the claimed neurostimulator because both are configured to conduct neuromuscular monitoring and apply stimulation signals to the muscles of a patient’s body;

at least one pressure waveform sensor to detect pressure waveform signals produced by a patient’s muscle in response to the applied stimulation signals (see col. 15, para. 0072, Gozani). The disclosed detection of muscle response is considered to

anticipate the claimed pressure waveform sensor because both are capable of determining the waveform signals produced for ultimate detection of neuromuscular blockade;

a processor of the detected pressure waveform signals and a display of data, from the processor, related to the detected pressure waveform signals (see col. 9, para. 0047, Gozani). The disclosed monitor is considered to anticipate the claimed display of data because both contain an indicator to display or convey the results of the diagnostic process. In this connection, Gozani teaches a means of actuating diagnosing process and processing the detected waveform signal to facilitate neuromuscular monitoring.

With reference to claim 3, Gozani is considered to disclose:

the neuromuscular system wherein the data displayed through the display is selected from the group consisting of: raw pressure waveform signals detected through said at lease one pressure waveform sensor, amplitudes of the pressure waveform signals, and ratios of said amplitudes (see col. 15, para. 0072, Gozani). The disclosed amplitude attenuation is considered to anticipate the claimed data displayed because both groups of data are displayed and studied to identify specific muscle response features.

Referring to claim 4, Gozani is considered to teach:

the neuromuscular monitoring system further comprising an amplifier for amplifying the pressure waveform detected by said at least one pressure waveform sensor (see col. 13, para. 0062, Gozani). The disclosed amplifier is considered to

anticipate the claimed amplifier because both devices are configured to amplify the detected waveform.

With reference to claims 5 and 12, Gozani is considered to disclose:

the neuromuscular monitoring system comprising a controller connected to said at least one neuromuscular and to said at least one pressure waveform sensor, said controller incorporating the processor and display (see col. 4, para. 0015, Gozani). The disclosed controller is considered to anticipate the claimed controller because both are in electrical communication with a processor and sensor.

Referring to claim 19, Gozani is considered to disclose:

providing at least one pressure waveform sensor (see col. 15, para. 0072, Gozani). The disclosed method of detecting the waveform is considered to anticipate the pressure waveform sensor because both detect the pressure waveform signals produced by a patient's muscle in response to the applied stimulation signals;

positioning said at least one pressure waveform sensor at a predetermined position of a patient's body, providing at least one electrode, positioning the at least one electrode at a predetermined position of the patient's body, and applying muscle-activating stimulation signals to the patient's body via said at least one electrode (see col. 2, para. 0008, Gozani). The disclosed method of positioning the electrodes on the predetermined position of the arm or hand is considered to anticipate the claimed predetermined positioning because both methods are the initial step in the phonomyographic method for neuromuscular monitoring using the specific stimulation strategy;

sampling pressure waveform signals detected by said at least one pressure waveform sensor in response to the applied muscle-activating stimulation signals (see col. 22, para. 0101, Gozani). The disclosed method of sampling the pressure waveform signals is considered to anticipate the claimed method because both sample stimulation signals applied to the patient's body in response to the applied muscle-activating stimulation signals;

processing the detected pressure waveform signals; and displaying data, from the act of processing, related to the detected pressure waveform signals (see col. 9, para. 0047, Gozani). The disclosed monitor is considered to anticipate the claimed display of data because both contain an indicator to display or convey the results of the diagnostic process. In this connection, Gozani teaches a means of actuating diagnosing process and processing the detected waveform signal to facilitate neuromuscular monitoring.

With reference to claims 20, 22, and 23, Gozani is considered to disclose: processing the detected pressure waveform signals comprises measuring amplitudes of the detected pressure waveform signals (see col. 15, para. 0072, Gozani). The disclosed amplitude attenuation is considered to anticipate the claimed data displayed because both groups of data are displayed and studied to identify specific muscle response features.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3762

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gozani. Gozani is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed laptop and pocket computer. It would have been an obvious matter of design choice to use the teachings of Gozani with a laptop or pocket computer, since the devices are not recited in a manner to show a patentably distinction from what is discussed in the prior art.

Claims 8 and 9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gozani. Gozani discloses the claimed invention except for a plurality of neurostimulators and pressure waveform sensors associated with different muscles of the patient. It would have been obvious to one having ordinary skill in the art a the time the invention was made to use the neurostimulator and pressure waveform of Gozani and associate them with different muscles of the patient, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (see St. Regis Paper Co. v. Bemis Co., 193 USPQ 8).

Claims 10 and 11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gozani. Gozani discloses the claimed invention except for the frequency bandwidth range. It would have been obvious to one having ordinary skill in the art a the time the invention was made to select frequency of between 2Hz and 10Hz, since I has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art (see *In re Aller*, 105 USPQ 233).

***Allowable Subject Matter***

Claims 13-15 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 16-18 are deemed allowable. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not acquire a reference signal before the injection of the muscle relaxant and after the relaxant is injected. The prior art of record does not acquire these reference signals by applying a single stimulation signal via the stimulation electrodes and the reference signals from the pressure waveform sensors which are sampled and which peak to peak amplitudes are measured and stored.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Dana D. Greene*  
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*G. M.*  
George Manuel

Primary Examiner